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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,321	02/17/2004	Roland Buelow	A-64360-2/TAL/NHT	1116

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DORSEY & WHITNEY LLP
555 CALIFORNIA STREET, SUITE 1000
SUITE 1000
SAN FRANCISCO, CA 94104

EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,321	BUELOW ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 1/25/06 is acknowledged and has been entered.

Claims 1-31 are pending and are presently being examined.

2. Applicant is required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NO for sequences disclosed in the specification (for example, the specification at line 4 of [0010] and in the brief description of the drawings for the sequence shown in the figures.

3. Applicant is reminded that with regard to Applicant's amendment to the specification filed 8/16/04, the direction to amend the specification at paragraph numbers appears to be off by one paragraph number, i.e., for example, the replacement paragraph [0008] that Applicant directs be replaced, is actually paragraph [0009] in the specification, and so forth for the other replacement paragraphs.

4. The terminal disclaimer filed on 10/11/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,696,545 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following are new grounds of objection or rejection necessitated by Applicant's amendment filed 1/25/06.

5. Claims 29-31 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP 608.01(n).

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9 and 10 of copending Application No. 10/376,647 in view of U.S. Patent No. 5,702,946 A, WO 93/03764 and U.S. Patent No. 6,828,415 B2.

This is a provisional obviousness-type double patenting rejection.

Claims 9 and 10 of copending Application No. 10/376,647 are drawn to a pharmaceutical composition for reducing gastrointestinal toxicity induced by cytoablative therapy comprising the peptide recited in instant claim 1 and further comprising an agent that is one of an anti-diarrheal agent, an anti-inflammatory agent or an analgesic agent, and in the case of claim 10, to an anti-diarrheal agent.

Claims 9 and 10 of copending Application No. 10/376,647 do not recite wherein a pharmaceutically acceptable medium is an excipient that is mannitol, nor wherein the oligopeptide has the structural formula recited in instant claim 7, i.e., has D-amino acid residues except at position 9.

U.S. Patent No. 5,702,946 A discloses pharmaceutical compositions comprising polypeptides that are antibodies to IL-8 that are used to treat inflammatory disorders such as organ failure, septic shock ARDS, IBD and bacterial pneumonia, said pharmaceutical compositions comprising mannitol (especially abstract and column 14 at lines 1-21).

WO 93/03764 teaches that peptides are more stable when the D-amino acid form is used and that the peptide sequences can be modified by carboxy terminal amidation or other modifications at the carboxy or amino termini (especially page 17 at lines 27-37 page 4 at lines 28-33, page 15 at lines 10-24).

U.S. Patent No. 6,828,415 B2 discloses a decapeptide with a terminal acid amide group that is used in the form of its acetate salt for pharmaceutical administration (especially column 1 at lines 10-15).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the peptide recited in claims 9 and 10 of '647 in a pharmaceutical composition comprising the excipient mannitol as disclosed by U.S. Patent No. 5,702,946 A, to have made the peptide with any or all of the amino acid residues as the D-amino acid form, and to have formulated the peptide as a carboxy-terminal amide as taught by WO 93/03764 or to have formulated it as the acetate salt of an amide as disclosed by U.S. Patent No. 6,828,415 B2. It would have been prima

facie obvious to one of ordinary skill in the art at the time the invention was made to have made a carboxy-terminal amide version of the oligopeptide as taught by WO 93/03764 or acetate salt of an amide as disclosed by U.S. Patent No. 6,828,415 B2 at the carboxy-terminal position.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to inhibit T cell proliferation and T cell mediated lysis, *i.e.,* forms of inflammation, because U.S. Patent No. 5,702,946 A discloses pharmaceutical compositions comprising other polypeptides that are anti-inflammatory agents in a pharmaceutical composition comprising the excipient mannitol, and one of ordinary skill in the art at the time the invention was made would have been motivated to have used the L amino acid residue form of the peptide or to have substituted D-amino acid residues at any or all positions in the oligopeptide. One of ordinary skill in the art at the time the invention was made would have been motivated to have made the acetate salt of an amide or amide versions of the oligopeptide because WO 93/03764 teaches formulating peptides as carboxy-terminal amides and U.S. Patent No. 6,828,415 B2 discloses making an acetate salt of an amide for use in pharmaceutical compositions.

In addition, the oligopeptides of instant claims 1-7 and 11-28 are encompassed by the composition comprising the said oligopeptide of copending Application No. 10/376,647, and the composition comprising the oligopeptides of instant claims 8-10 and 29-31 encompass the composition of claims 9 and 10 of copending Application No. 10/376,647.

8. Claims 1-31 are directed to an invention not patentably distinct from claims 9 and 10 of commonly assigned copending Application No. 10/376,647, as enunciated supra at item #7 of this Action.

9. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/376,647, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
April 20, 2006

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600